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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,477	01/02/2002	Yoshihiro Takai	18721-7053	5209
23639	7590	06/24/2004	EXAMINER	
BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO, SUITE 1800 SAN FRANCISCO, CA 94111-4067			CHURCH, CRAIG E	
			ART UNIT	PAPER NUMBER
			2882	

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,477

Applicant(s)

TAKAI ET AL.

Examiner

Craig E. Church

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,22-30,34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20,22-30,34-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-7, 9-19 22-30 and 34-39 are rejected under 35 U.S.C. 102(a) as being anticipated by Kunieda et al (6307914). Kunieda teaches a pursuing (tracking) radiation therapy system comprising a therapy x-ray beam generating LINAC 15, patient support couch 20 (called a base), first and second x-ray imaging systems 21a-f and 22a-f, markers 17 indicating tumor location, data processing means 24-32 for receiving data from the imaging systems and determining the dynamic location of the tumor and various controllers for adjusting the therapy apparatus in response to the detected tumor position. Lines 15-28 of column 9 explain such control includes gating source 15 on and off. Line 59 of column 15 to line 11 of column 16 teach that such control includes moving the patient couch (base). Lines 14-36 of column 16 mention that such control includes adjusting a multileaf collimator 15a. Lines 59-62 of column 11 reveal that the markers may be of various shapes and may be implanted in the patient. Lines 40-62 of column 16 suggest the use of multiple markers, and lines 36-51 of column 17 describe markers on the exterior surface of the patient which are imaged by TV cameras 1 and 2. Kunieda's imaging cycle

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includes at least two phases, ie first acquiring an image with system 21 and then acquiring an image with system 22. This cycle is repeated throughout the tracking process, and images may be acquired from other system positions as well. See lines 41 et seq of column 7. Columns 1 and 2 of Kunieda describe (prior art) tracking radiation therapy using the anatomy of a patient to locate a region to be treated and enabling radiation therapy.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunieda in view of Cosman (6459769). Kunieda does not suggest use of two beam collimators in series. Cosman discloses radiation therapy apparatus comprising first 12/16 and second 20/24 multileaf collimators, and it would have been obvious to equip the Kunieda device with a second MLC as taught by Cosman to enhance its ability to shape and control the therapy beam.

Applicant's arguments filed March 22, 2004 have been fully considered but they are not persuasive. Applicant's assertions regarding claims 1 and 10 are in error. Lines 54 of column 7 to line 47 of column 8 of

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Kunieda explicitly explain how a relationship is established between a patient tumor 17 and marker 18.

Regarding claim 11 applicant has grossly misrepresented the Kunieda patent in stating that its multileaf collimator simply opens and closes. In fact lines 25-35 of column 16 explain

In the above embodiment 1, on/off control of the medical treatment beam 16 of the linac 15 is performed by obtained three-dimensional coordinates of the tumor marker 17. However, as shown in FIG. 20, if the moving body pursuit irradiating device is constructed such that the multi-leaf collimator 15a is opened and closed by the multi-leaf collimator control section 35 by performing an *inverse* operation from a moving amount of the tumor marker 17 and an irradiating field is dynamically controlled, *the position of the tumor can be set to an irradiating object of the medical treatment beam at any time.*

In other words, inverse opening and closing means that as the tumor moves across the treatment beam, one side of the collimator opens while the other side of the collimator closes so that the tumor remains centered in the beam.

Regarding claim 25, lines 66 of column 8 et seq explain how the tumor is tracked in three dimensions as the intersection of two straight lines which tracking signal influences enablement of the treatment beam, coordinated movement of the patient support, coordinated movement of the multileaf collimator etc.

Regarding claims 29 and 30, Kunieda's imaging cycle includes at least two phases, ie first acquiring an image with system 21 and then acquiring an image with system 22. This cycle is repeated throughout the tracking process, and images may be acquired from other system positions

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as well. See lines 41 et seq of column 7. Lines 14-36 of column 16 mention that control includes adjusting a multileaf collimator 15a.

Regarding claims 34-36, columns 1 and 2 of Kunieda describe (prior art) tracking radiation therapy using the anatomy of a patient to locate a region to be treated and enabling radiation therapy.

Regarding claims 37-39, Kunieda's imaging cycle includes at least two phases, ie first acquiring an image with system 21 and then acquiring an image with system 22. This cycle is repeated throughout the tracking process, and images may be acquired from other system positions as well. See lines 41 et seq of column 7. In these claims "phase" refers to parts of the imaging cycle and not to phases of patient motion etc. Contrary to applicant's assertions, Kunieda's invention is explicitly based on tracking internal marker 17. See lines 66 et seq of column 8.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Craig E. Church at telephone number (571) 272-2488.



Craig E. Church
Primary Examiner